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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Cardiovascular and Renal Drugs Advisory Committee; Notice of Meeting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

*Name of Committee:* Cardiovascular and Renal Drugs Advisory Committee.

*General Function of the Committee:* To provide advice and recommendations to the agency on FDA's regulatory issues.

*Date and Time:* The meeting will be held on October 22, 1998, 9 a.m. to 5:30 p.m., and October 23, 1998, 9 a.m. to 3 p.m.

*Location:* National Institutes of Health, Clinical Center, Bldg. 10, Jack Masur Auditorium, 9000 Rockville Pike, Bethesda, MD. Parking in the Clinical Center is reserved for Clinical Center patients and their visitors.

*Contact Person:* Joan C. Standaert, Center for Drug Evaluation and Research (HFD-110), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 41 9-259-6211, or John M. Treaty (HFD-21), 301-827-7001, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12533. Please call the Information Line for up-to-date information on this meeting.

*Agenda:* On October 22, 1998, the committee will discuss guidelines for the study of congestive heart failure. On October 23, 1998, the committee will discuss new drug application (NDA) 20-873, Hirulog (bivalirudin, The Medicine's Co.), injection for anticoagulation in patients undergoing percutaneous transluminal angioplasty.

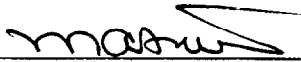
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*Procedure:* Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by October 14, 1998. Oral presentations from the public will be scheduled between approximately 9 a.m. and 10 a.m. on October 23, 1998. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 14, 1998, and submit a brief statement of the general nature of the evidence or arguments they

wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

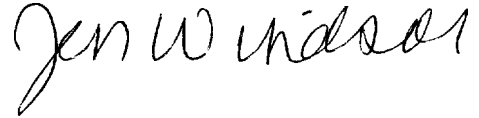
Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: September 16, 1998



Michael A. Friedman  
Deputy Commissioner for Operations

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL



[FR Dot, 98-'??'?? Filed '??-'? '-98; 8:45am]

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